

The VacScene

Public Health – Seattle & King County Immunization Newsletter Volume 11, Number 4 July/August 2005

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~Thimerosal and Autism:
Talking Points for Health Care Practitioners

The VacScene

Public Health - Seattle & King County Communicable Disease, Epidemiology and Immunization Section

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The VacScene is a publication of Public Health – Seattle & King County written for health care practitioners. Content is consistent with the most current recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP).

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Vaccines, Autism, and Parental Hesitancy

Childhood vaccines are in the media spotlight following the promotion of the book *Evidence of Harm*, by the New York Times contributing author, David Kirby, and a well-publicized commentary written by Robert F. Kennedy, Jr. ("Deadly Immunity" published by *Salon* and *Rolling Stone*). Both publications strive to make a case that links the vaccine preservative thimerosal to autism, using flawed arguments that, none the less, sound convincing to the average reader.

Background

The controversy linking MMR vaccine to autism began in 1998 after Dr. Andrew Wakefield and colleagues published a case study of only 12 children with developmental disorders. For eight of these children, the onset of their behavioral problems was temporally associated with MMR vaccination. The study has been widely discounted, and ten of the original 13 authors have since recanted, stating that the data from the study were insufficient to establish a causal link between MMR vaccine and autism.

Some researchers and parent-led organizations have continued to pursue a connection between vaccines and autism, stating that the vaccine preservative thimerosal (ethylmercury) may be the cause of autism and prodding legislative involvement to ban the ingredient from vaccines. The Centers for Disease Control and Prevention (CDC), the Institute of Medicine (IOM), and medical professional organizations defend the safety of vaccines citing several large studies, and have refuted the methods of research supporting a causal vaccine-autism link. Studies were reviewed by the IOM in 2001 and 2004 (www.iom.edu). A July 19, 2005, press conference was held on the topic by CDC in conjunction with several professional organizations. (Visit: www.cdc.gov/od/oc/media/transcripts/t050719 to read the transcript).

The controversy about thimerosal is a public health concern. Parents trying to sort out the facts are understandably confused by the differing points of view. Many parents may not realize thimerosal is no longer an ingredient as a preservative in recommended childhood vaccines, except for one formulation of influenza vaccine. The media will often try to find opposing views in discussion of issues. Parental misgivings about vaccines may be heightened by inflammatory websites that question the safety of vaccines.

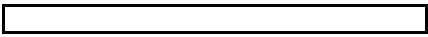
Parental concerns about vaccine safety can lead to lower immunization rates and increase public vulnerability to diseases. Infants and children not able to receive or complete a series of vaccine are protected by herd immunity in the community; this protection can easily be eroded.

Continued on page 3...

Thimerosal Fact Sheet

To assist practitioners with inquiries from their patients and the public, Public Health has developed and enclosed a fact sheet with this issue of *The VacScene*, entitled, "Thimerosal and Autism: Talking Points for Health Care Practitioners." The fact sheet is designed for health care practitioners, and is not in a format for dissemination to the general public.

Currently, all routinely recommended vaccines for children are available in thimerosal-free formulations, or contain only trace amounts of thimerosal, except multi-dose vials of inactivated influenza vaccine. Multi-dose vials require thimerosal because of the potential risk of bacterial contamination that occurs when vials are punctured multiple times. See the Thimerosal and Childhood Vaccines Table on page 2 in this *VacScene* issue.



Meningococcal Vaccine Shortage

Currently there is a temporary national shortage of vaccine supplies for Meningococcal Conjugate Vaccine (MCV4), known as Menactra, and Meningococcal Polysaccharide Vaccine (MPSV4) known as Menomune. At this time the manufacturer, Sanofi Pasteur, is limiting orders for both Menactra and Menomune to 20 doses per order per month from each health care entity vaccine ordering unit, total of 40 doses per month if ordering both vaccines. New Menactra orders are not expected to be shipped until September 21. Providers can contact Sanofi-Pasteur directly at 1-800-822-2463 for more information about order limitations.

*During the limited time frame of short supply - Public Health - Seattle & King County (PHSKC) recommends health care practitioners consider using **Menactra preferentially for persons (11-55 years) at increased risk for meningococcal disease:***

- Persons with terminal complement component deficiencies
- Persons who have anatomic or functional asplenia
- Microbiologists with routine exposure to isolates of *N. meningitidis*
- Persons who travel to or reside in countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged
- Entering college freshmen who will live in dormitories

When supplies permit vaccination of broader groups with Menactra, PHSKC suggests the following priority order:

1. All entering college freshmen
2. Those entering high school (approx. age 15 years)
3. 11-12 year olds

Menomune may be considered as an appropriate alternative for all of these groups when Menactra is unavailable. Link to the CDC recommendations for meningococcal vaccines at: www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.

Tdap to Prevent Pertussis in Adolescents

Infants with pertussis have the highest morbidity and mortality, and frequently are infected by an adolescent or adult with relatively mild symptoms often not recognized as pertussis. Recently, two new vaccines have been approved: Boostrix (for ages 10-18 years), and Adacel (for ages 11-64 years) to protect against tetanus, diphtheria and pertussis. Adacel (Tdap) contains the same components as pediatric Daptacel (DTaP), but the diphtheria toxoid and one of the pertussis components are in reduced quantities. It is hoped these vaccines will decrease transmission to unprotected infants who are too young to have completed the primary vaccination series.

The following is a preliminary summary of the June 30th, 2005 Advisory Committee on Immunization Practices (ACIP) recommendations for Tdap which **are not official** until they are published in CDC's *Morbidity and Mortality Weekly Report*. The ACIP has not yet made a recommendation on use of the vaccine in adults or health care providers, however Adacel is licensed for administration in adults 64 years of age and under.

Provisional Recommendations for Tdap* (Tdap licensed for only one dose)

- ◆ 11-12 yr olds should receive one dose of Tdap instead of Td**
- ◆ 13-18 yr olds who missed the booster dose of Td should receive one dose of Tdap instead of Td**
- ◆ 11-18 yr olds who received a Td booster are encouraged to receive one dose of Tdap** (5 year interval is encouraged, but intervals as short as 2 years were found to be safe)

***Tdap is not currently available through the VFC program.**

**** If the primary DTaP vaccination series was completed.**

Thimerosal and Childhood Vaccines Table

The chart below summarizes the thimerosal content in routinely used vaccines. The availability of particular vaccines through the VFC program is determined by the Washington State Department of Health VFC program.

Childhood Vaccines	Age	Does it Contain Thimerosal as a Preservative ?
DTaP (Daptacel)	6 wks – 7 yrs	No (Never contained thimerosal)
DT Single dose	6 wks – 7 yrs	No*
DT Multi-dose vial	6 wks – 7 yrs	Yes**
Td (Decavac)	>7 yrs	No*
Tdap (Adacel)	11-64 yrs	No (Never contained thimerosal)
Hepatitis A (Havrix)	>2 yrs	No
Hepatitis B (Recombivax)	>6 wks	No
Hib (ActHib)	6 wks-5 yrs	No (Never contained thimerosal)
Meningococcal Conjugate (Menactra)	11-55 yrs	No
Meningococcal Polysaccharide (Menomune) Single dose vial	>2 yrs	No
Meningococcal Polysaccharide (Menomune) Multi-dose vial	>2 yrs	Yes**
MMR	>12 mos	No (Never contained thimerosal)
Pneumococcal Conjugate (Prevnar)	6 wks-5 yrs	No (Never contained thimerosal)
Pneumococcal Polysaccharide (Pneumovax 23)	>2 yrs	No
Polio (IPV/IPOL)	6 wks-18 yrs	No (Never contained thimerosal)
Varicella (Varivax)	>12 mos	No (Never contained thimerosal)
Influenza (Fluzone) Single dose vial	6-35 mos	No
Influenza (Fluzone) Multi-dose vial	>3 yrs	Yes**
Influenza (FluMist)	5-49 yrs	No (Never contained thimerosal)

*Contains a trace amount of thimerosal (<0.00012%) which is <0.3mcg ethylmercury per 0.5ml dose.

**Thimerosal is approximately 50% mercury by weight. A 0.01% solution of thimerosal contains 25 mcg of mercury per 0.5 ml dose.

Cont'd from pg 1...*Vaccines, Autism, and Parental Hesitancy*

Vaccine Hesitancy Data

Local data about vaccine-hesitant parents is sketchy. Data from Washington State Department of Health show an increase in the number of King County children exempt from at least one immunization required for school entry from 2.9% in 2000 to 4.2% in 2004-05. Of 578 schools in King County, 25% had an exemption rate of 5% or greater for the 2003-04 school year; 26 schools had exemption rates greater than 10% for the 2003-04 school year.

Phillip J. Smith et al¹, in a study using National Immunization Survey data, found King County ranked 8th of 50 counties nationally for children receiving no vaccines. The study examined the characteristics of parents with completely unimmunized children 19-35 months of age. This group refused vaccinations because of philosophical objections rather than economic or educational limitations. Smith found these parents tended to be resistant to physician influence over their vaccination decisions, be over 30 years of age, have an income of at least \$70,000, and have a college degree.

Communication with Vaccine-Hesitant Parents

In a study by Salmon et al., beliefs held by vaccine-hesitant parents included:²

1. The vaccine might cause harm (68%)
2. Vaccines overload the immune system (49%)
3. Perception that the child is not at risk for the disease (37%)
4. The diseases are not dangerous (20%)
5. The vaccine might not work (13%)

When claiming vaccine exemptions prior to school entry, parents were more apt to have:²

1. Concerns that vaccines might cause harm
2. Low perceived vaccine safety and efficacy
3. Low level of trust in government
4. Low perceived susceptibility to and severity of the diseases
5. Less confidence in medical, public health and government sources for vaccine information
6. Confidence in alternative medicine professionals

Confronted with the potential for autism, injury, or death resulting from vaccination, parents are comfortable with not vaccinating because they believe their children are unlikely to contract these diseases, and with the proper preventive care, their children will not develop complications if infected.

Parents are less willing to take any risk with their children especially when herd immunity becomes the strongest argument for vaccination. Douglas S. Diekema, MD, MPH of the American Academy of Pediatrics Committee on Bioethics comments on the ethical conflict health care practitioners face when individual and community needs differ:

"The decision to refuse to immunize a child is **made less risky because others have created an environment in which herd immunity will likely keep the unimmunized child safe**. These individuals place family interest ahead of civic responsibility... such parents...reject what many would consider to be a moral duty..."³

Physicians might find the physician-patient relationship challenged by the media's coverage of controversy, and may find it difficult to adequately address parents' questions.

Research supports the assumption that communicating vaccine safety to parents should be a priority, especially about thimerosal, because of its increased legislative and media attention. However, there is insufficient data to know what strategy would be effective to facilitate acceptance of immunizations among vaccine-hesitant parents.

Allison Kennedy et al⁵ describe using basic information about vaccine-preventable diseases, and the safety and importance of routine childhood vaccinations to help reduce parent's opposition to compulsory vaccinations.

Understanding the parental perspective and beliefs can be helpful in addressing their questions and concerns. See the article, "**Experts Forum on Vaccine Hesitancy**" on page 4 in this issue of *The VacScene*.

Bruce Gellin, MD, Executive Director of the NNii, is concerned that **even a small decrease in the current immunization rates may lead to a resurgence of vaccine-preventable diseases**.⁵

Vaccine-hesitancy may represent a threat to the country's immunization program, and yet much is still unknown about the issue. Questions about vaccine-hesitancy remain: How do these parents make vaccine decisions? What are trusted sources of information? What are compelling reasons for vaccination? Can people be motivated by the benefits of herd immunity? Are "moral duty" discussions appropriate or effective?

1. Smith, P.J., Chu, S.Y. & Barker, L.E., (2004) Children Who Have Received No Vaccines: Who Are They and Where Do They Live? *Pediatrics*, 114:187-95
2. Salmon, DA, et al. (2005). Factors associated with refusal of childhood vaccines among parents of school-aged children: A case-control study. *Archives of Pediatrics and Adolescent Medicine* 2005; 159:470-476.
3. Diekema, D.S., (2005). Responding to Refusals of Immunization of Children. *Pediatrics*, 115; 1428-1431.
4. Kennedy, A.M., et al. Vaccine Beliefs of Parents Who Oppose Compulsory Vaccination, Public Health Reports, Vol. 120, 252-258, May-June 2005
5. Gellin, B., (2005). Misconceptions about value of vaccines. *AMA News Brief*.

VFC News

Vaccines for Children Program

July 2006: Varicella Required for School

The new school requirement for varicella vaccination, effective July 1, 2006, will apply to children entering kindergarten, 6th grade, and all children 19 months and older who attend licensed child care or preschool.

Varicella vaccine is stored in the freezer, and has special ordering, handling and storage instructions. Health care providers who wish to offer varicella vaccine should contact the VFC Program at (206) 296-4774 for more information, or refer to the varicella handling instructions in the VFC Provider Manual. *Please note: smaller, dorm-style units with freezers inside the refrigerator cannot be used for varicella vaccine storage.*

Return Services Requested

Experts Forum on Vaccine Hesitancy

On May 24th, Public Health – Seattle & King County (PHSKC) held a forum of health care practitioners (pediatricians, naturopaths, family practice physician and public health staff) to elicit their perceptions of vaccine hesitancy among parents of young children. **A summary of the Experts Forum is enclosed** in this issue of *The VacScene*, and includes an outline of key approaches that have been successful when working with vaccine-hesitant families. Public Health welcomes continued feedback from health care practitioners on vaccine hesitancy. If you would like to comment please contact, Krista.Rietberg@metrokc.gov or call (206) 296-4980.

Highlights

New Class for Parents

Increasing numbers of parents have questions and safety concerns about vaccines. To address this issue, Public Health developed “Vaccine Information for Parents”, a class offered at no cost that covers general information about vaccines, the diseases they prevent, and controversial vaccine topics (e.g. thimerosal). The material is presented by a team of health practitioners, and encourages discussion in a format similar to preparation for childbirth classes. For more information, call Julie Nugent-Carney at (206) 205-8605.

CDC Immunization Update Satellite Course

The CDC’s *Immunization Update 2005* satellite broadcast (July 28th) is now available on the CDC website. To obtain a DVD, visit www.cdc.gov/nip/ed in September. Continuing Education will be available by registering and completing an evaluation found at www.phppo.cdc.gov/phtnonline (expires August 29, 2005). For full accreditation statements, including information about pharmacy credit, go to www.cdc.gov/nip/ed/ce.htm. The live web cast will be available for one month after the broadcast and can be found at: www.phppo.cdc.gov/PHTN/webcast/immup2005.

2005 Laminated Immunization Schedule

To order the current pocket-size 2005 laminated immunization schedule call Healthy Mothers, Healthy Babies at 1-800-322-2588.

VIS for Meningococcal Vaccines

On April 4, the National Immunization Program posted an interim VIS for meningococcal vaccine. This new VIS (4/4/05) replaces the previous meningococcal VIS (7/28/03). Substantial revisions incorporate information about the newly licensed meningococcal conjugate vaccine (Menactra). Since the previous VIS was designed for Menomune, it may be used for patients who receive that vaccine (but it may *not* be used for patients who receive Menactra).

The Washington State Department of Health anticipates meningococcal conjugate vaccine will be added to the Vaccine Injury Compensation Program later in 2005. When this occurs, the interim VIS will be republished. To read the most recent ACIP statement discussing recommendations for the two meningococcal vaccines, visit: www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.

New Site for Reporting Adverse Reactions to Vaccines

The Vaccine Adverse Event Reporting System (VAERS) is a national post-marketing safety surveillance program. Recently, VAERS changed its web address to www.vaers.hhs.gov (previously www.vaers.org), but the phone number (1-800-822-7967) remains unchanged. For continued vaccine safety, it is important for health care practitioners to report adverse events following vaccination, whether or not they are considered related to a vaccine.

Available in alternate formats